REMARKS

Upon entry of the present amendment, claims 7, 8, 18, 20-29, 33, 38, and 39 will be pending. Claims 1-6, 9-17, 19, 30-32, and 34-37 have been canceled without prejudice. Claims 20–29 have been withdrawn. Claims 7, 8, 20 and 26 have been amended to correct punctuations and claim dependencies. Applicants have added new claims 38 and 39, which are supported throughout the specification, for example, at page 21, lines 29-30; and at page 23, lines 5-6.

Withdrawn Rejections

Applicants note with appreciation that the Office has withdrawn the previous rejections under 35 U.S.C. § 103.

35 U.S.C. § 103

The Office rejected claims 1, 3, 7-8, 17-18, and 33 as allegedly obvious over Plotkin et al. (EP 0389286 B1, "Plotkin") in view of Endresz et al. (Vaccine, 19: 3972-3980, 2001; "Endresz") and Mach et al. (Journal of Virology, 11881-11892, 2000; "Mach").

As an initial matter, applicants note that the Office Action states (at page 3) that the claims are rejected under 35 U.S.C. § 102(b). However, the Office Action asserts (at page 6):

> ... in view of the teachings of Plotkin, it would have been obvious for one of ordinary skill in the art, at the time the claimed invention was made, to replace the HCMV gB subunit of gcII adenovirus of Plotkin with plasmid gM (UL100) and gN (UL73) of Mach for priming with said plasmids and boost with their recombinant proteins as taught by Endresz for a vaccine in humans for inducing neutralizing antibodies against HCMV with a reasonable expectation of success.

Thus, applicants assume that the Office meant to reject the claims under 35 U.S.C. § 103, not 35 U.S.C. § 102(b). Given this assumption, applicants traverse the obviousness rejection based on the following comments and the attached declaration of an expert in the field of CMV research, Edward S. Mocarski, Jr., Ph.D. ("the Mocarski Declaration," a copy of which is attached as "Exhibit A"), in which Dr. Mocarski explains that the gB glycoprotein is very different from the gcII (gM/gN) complex, and that experimental results and suggestions relating to gB cannot be extrapolated to hold true for the gcII complex.

The present claims are directed to, *inter alia*, a composition including a plurality of nucleic acid molecules (e.g., plasmids) comprising nucleotide sequences encoding different human cytomegalovirus (HCMV) polypeptides that induce a neutralizing antibody response. The HCMV polypeptides comprise glycoprotein M (gM), or an antigenic fragment of gM, and glycoprotein N (gN), or an antigenic fragment of gN.

Plotkin discloses administering a recombinant adenovirus having a gene encoding the HCMV glycoprotein B (gB) to hamsters, which produced neutralizing antibody to HCMV (see, e.g., Example 3). Although Plotkin suggests in passing (see, e.g., column 8, lines 3-7) that its recombinant adenovirus expression system could be used to express other HCMV subunit proteins, e.g., gcII, the reference does not contain any actual examples of an adenovirus that expresses gcII (i.e., the gM/gN complex), or any example of such an adenovirus being administered to any subject. In fact, when Plotkin filed his priority application in 1989 little was known about exactly what glycoproteins were part of the so-called gcII complex.

Endresz describes administering a plasmid encoding gB to mice. There is nothing in this reference about gN and gM.

Mach suggests (see, e.g., Abstract) that gM and gN form a complex, and that the gM/gN complex may be an antigenic target of antiviral antibody responses. However, while Mach discloses that the gM-gN protein complex "may represent a major antigenic target of antiviral antibody responses," Mach fails to suggest that gM and gN could be used as a nucleic acid-based vaccine as presently claimed. In addition, Mach ends his paper by stating that "[f]uture experiments will be directed towards defining the functional and immunological properties of the gM-gN complex" (page 11891, left col.). Moreover, the gM- and gN-expressing plasmids disclosed in Mach were used solely to express these polypeptides *in vitro*.

In essence, none of these references discloses any data demonstrating or suggesting that gcII (i.e., gM and gN) could be successfully used as a nucleic acid-based vaccine to induce a neutralizing antibody response against CMV. Nevertheless, the Office Action asserts (at pages 6 and 7) that those skilled in the art would have reasonably expected that plasmids expressing gN and gM could be used as a DNA vaccine, apparently based on the gB data disclosed in Plotkin

and Endresz, and the suggestion in Mach that gcII may be an antigenic target of antiviral antibody responses.

Applicants disagree that those skilled in the art would have had any expectation that a nucleic acid-based vaccine based on gM and gN would have been successful. Applicants support this position with the Mocarski Declaration ("Exhibit A"), in which Dr. Mocarski explains why those skilled in the art would not have expected a gM/gN nucleic acid-based vaccine to work, and why data pertaining to gB cannot be extrapolated to gM and gN. As the Declaration elucidates (see paragraph 3), gB is a very different protein, both structurally and functionally, from gcII. In particular, unlike gB, gcII is extremely hydrophobic. This hydrophobicity renders gcII difficult to express and an unsuitable candidate for a subunit vaccine. Thus, as Dr. Mocarski stated in his Declaration (at paragraph 4):

> Due to the unique properties of gcII, it would not have been obvious that any DNA or other vaccine based on expression of gcII within cells would have worked before the filing of the present application. Further, one could not have reasonably concluded that, because CMV vaccines based on other glycoproteins such as gB had been generated or described in the literature, a DNA vaccine based on gcII would also have worked to induce a neutralizing antibody response in a subject.

Moreover, as set forth in the Declaration (see paragraph 5), prior to the present invention, there had been no reported successful attempt to generate any kind of a CMV vaccine based on gcII. Certainly, the Office has not cited a single reference that describes an actual vaccine based on gcII. The present specification, on the other hand, discloses actual data (see, e.g., Example 2) showing that administering a combination of gM- and gN-expressing nucleic acid molecules to rabbits can produce a synergistic neutralizing antibody response *in vivo*. This result was unexpected, at least in part, because of the reasons stated in the Declaration.

In view of the foregoing, applicants submit that, based on the teachings of Plotkin, Endresz and Mach, individually or in combination, it would not have been obvious to arrive at applicants' DNA vaccine based on gM and gN. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

Applicants respectfully request that all claims be allowed. Applicants do not concede any positions of the Examiner that are not expressed above, nor do applicants concede that there are not other good reasons for patentability of the presented claims or other claims.

The extension fee in the amount of $555 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 07917-0190001.

Respectfully submitted,

Date: March 2, 2009

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Exhibit A

Attorney's Docket No.: 07917-0190001 / UMMS 03-30

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Lu et al.	Art Unit	: 1632
Serial No.	: 10/789,247	Examiner	: Magdalene K. Sgagias
Filed	: February 27, 2004	Conf. No.	: 9906
Title	: COMPOSITIONS AND METHODS FOR CYTOMEGALOVIRUS TREATMENT		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF EDWARD S. MOCARSKI, JR., PH.D.
UNDER 37 C.F.R. § 1.132

I, Edward S. Mocarski, Jr., declare the following:

1. Because of my own work, I am familiar with cytomegalovirus (CMV) antigens, the various known CMV glycoproteins, including glycoprotein complex I (gcI), which includes glycoprotein B (gB) and glycoprotein complex II (gcII), which includes glycoproteins M and N, and related vaccines. My *curriculum vitae* is attached as Appendix A.

2. I have reviewed the patent application captioned above ("the present application").

3. It is well known to those skilled in the CMV field that gB is a very different protein from gcII. First, while gB is a monomeric protein, gcII refers to a dimeric complex comprising the CMV glycoprotein M (gM) and CMV glycoprotein N (gN). gM is composed of multiple membrane-spanning domains and associates with gN. gM and gN assemble in a distinct location from gB in the cytoplasm of CMV-infected cells as a component of the envelope of mature virions. The gcII complex has a distinct structure, and plays an essential function in viral infection that is completely unique from that of gB.

Second, gcII is extremely hydrophobic. Thus, unlike gB, which has a single hydrophobic membrane-spanning domain and a hydrophilic ectodomain, gcII is tightly associated within membranes. gcII cannot be readily expressed as a secreted or purified protein because of this extensive hydrophobic character. Because of these significant differences between gB and gcII, data pertaining to gB (e.g., expression of gB using an expression system; or ability of gB to induce a neutralizing antibody response in a subject) cannot be reasonably extrapolated to gcII.

For example, gcII would never be a candidate for a subunit vaccine, but needs to be expressed within cells and displayed on cellular membranes to be a component of a vaccine.

4. Due to the unique properties of gcII, it would not have been obvious that any DNA or other vaccine based on expression of gcII within cells would have worked before the filing of the present application. Further, one could not have reasonably concluded that, because CMV vaccines based on other glycoproteins such as gB had been generated or described in the literature, a DNA vaccine based on gcII would also have worked to induce a neutralizing antibody response in a subject.

5. To the best of my knowledge, there has been no reported successful attempt to generate any type of a CMV vaccine based on gcII prior to the work done by Dr. Shan Lu as described and claimed in the present application. Before Dr. Lu's work, it would not have been scientifically or practically obvious to generate a DNA vaccine based on gcII, or to have reasoned that such a vaccine would have worked.

6. I have reviewed an Office Action from the United States Patent and Trademark Office (USPTO) dated August 29, 2008 (the "Office Action") and the references cited therein (Plotkin et al., EP 0389286; Endresz et al, Vaccine, 19: 3972-3980, 2001; Mach et al., Journal of Virology, 11881-11892, 2000). In particular, I note that the USPTO has alleged that Dr. Lu's invention as recited in claims 1, 3, 7, 8, 17, 18 and 33 would have been obvious to those skilled in this field in view of Plotkin et al., Endresz et al. and Mach et al. For example, the USPTO states (at page 6 of the Office Action):

> Accordingly, in view of the teachings of Plotkin, it would have been obvious for one of ordinary skill in the art, at the time the claimed invention was made, to replace the HCMV gB subunit of gcII adenovirus of Plotkin with plasmid gM (UL100) and gN (UL73) of Mach for priming with said plasmids and boost with their recombinant proteins as taught by Endresz for a vaccine in humans for inducing neutralizing antibodies against HCMV with a reasonable expectation of success.

For at least the reasons set forth above, I disagree with the Office's assertion that the claims of the present application would have been obvious at the time of Dr. Lu's invention in view of these cited references.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: March 2, 2009

Edward S. Mocarski, Jr.

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Appendix A

CURRICULUM VITAE
Last modified: February 1, 2009
Date Printed: February 11, 2009

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MedImmune
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Robert W. Woodruff Professor
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Emory Vaccine Center
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Professor Emeritus, Stanford University School of Medicine.
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Date of Birth:	April 29, 1952
Place of Birth:	Belleville, New Jersey
Marital Status:	Married to Christine L. Martens, Ph.D.
	Daughter: Emily C. Mocarski (b. 1986)
Home Address:	1635 Mason Mill Rd. NE
	Atlanta GA 30329
	home (404) 929-6592 cell (650) 714-7005

Education and Employment Record (current appointments in bold):

Rutgers University, New Brunswick, New Jersey	A.B. Microbiology	1970-74
University of Iowa, Iowa City, Iowa	Ph.D. Microbiology	1974-79
USPHS Predoctoral Trainee in Cellular and Molecular Biology		1975-78
The University of Chicago, Chicago, Illinois	Postdoctoral	1979-83
USPHS Postdoctoral Trainee in Virology		1979-81
(University of Bologna Visiting Scientist, 1980)		
Leukemia Society of America Special Fellow		1981-83
Stanford University School of Medicine, Stanford, California		
Assistant Professor of Microbiology & Immunology		1983-89
Associate Professor of Microbiology & Immunology		1989-95
Chairman of the Department of Microbiology & Immunology		1995-99
Professor of Microbiology & Immunology		1995-06
Professor Emeritus		2006
Stanford University, Stanford, California		
Associate Dean of Research		2000-01
Emory University, Atlanta Georgia		
Robert W. Woodruff Professor of Microbiology & Immunology		2006-(on leave)
Emory Vaccine Center		2006-(on leave)
MedImmune, a wholly owned subsidiary of AstraZeneca		
Distinguished Fellow (senior management)		2008-present

Sabbatical leave:	SyStemix, Palo Alto, California	1990 (6 mo.)
	Aviron, Mountain View, California	1995 (6 mo.)

National/Foreign Review Panel Memberships (current membership in bold):
Institute of Medicine (National Academy of Sciences) Consultant, Committee on Review of Priorities in th National Vaccine Plan, 2008
NIH Reviewers Reserve/ad hoc reviews (1994-2008)
Topics in Virology Study Section (*ad hoc* 2007-2008)
UK MRC Virology Focus Strategy Review Group (2006-2008)
NIDOCD Review Panel on CMV-related Hearing Loss (2004)
NIH Virology B Study Section (2004)
Advisory Panel to Office of AIDS Res on Opportunistic Infections (1995-96)
NIH-NIAID Spec Review: Molec. & Struc. Appr. Antiviral Drug Design (1994)
NIH Experimental Virology Study Section (1990-1994)
NIH-NIAID Special Review - Animal Models of Human Viral Infections (1990)
NIH-NIAID Workshop on Opportunistic Infections in AIDS (1989)
NIH Small Business Administration Study Section (1988)
USDA Biotechnology Study Section (1986-88)

Ad Hoc Panel Member: United Kingdom MRC reviewer (1999, 2003-2008), NIH Clinical Sciences I Study Section (1985), NIH Site Visit Panels (1986, 1987), NIH Virology Study Section (1988), NIH-NIAID Microbiology and Infectious Disease Research Committee (1989), USDA-Hatch Grant Program Reviewer - University of Nevada (1989), NIH-NIAID Board of Scientific Counselors (1989), USDA Biotechnology Study Section (1989-95).

Reviewer: the USDA Biotechnology Study Section (1989-95) and the NIH-NIAID Board of Scientific Counselors (1989). I have also served as a reviewer or panel member for the Medical Research Council (United Kingdom), the Wellcome Foundation, the Australian Medical Research Council, the Canadian National Institute of Health, the Israel Science Foundation, the Veterans Administration, the National Foundation March of Dimes, the National Science Foundation and the Natural Sciences and Engineering Research Council of Canada.

Editorial Board (current membership in bold):
***Journal of Virology* (1991-2011), *Virology* (1991-2009)**, *J. Biol. Chem* (2001-2004 & 1994-1999), *Intervirology* (1986-1989)

Invited Reviewer:
Journals: *Science, Immunity, Cell, Journal of General Virology, Virus Research, Intervirology, Archives of Virology, Journal of Viral Immunology, Proceedings of the National Academy of Sciences, Journal of Clinical Microbiology, Journal of Infectious Diseases, New England Journal of Medicine, Journal of Experimental Medicine, Blood, Journal of Immunology, Journal of Interferon and Cytokine Research, Journal of Biological Chemistry*

Other Honors and Awards:
Maurice Hilleman Lecturer, The University of Chicago (2008)
Georgia Cancer Coalition Eminent Scholar (2006-2011)
Robert W. Woodruff Chair Professorship (2006-present)
Stanford University Fellow (2002-2004)
Pfizer Visiting Professor in Infectious Diseases, Univ of Oklahoma (2001)

Elkin's Lecture, Emory University (1999)
ASM Foundation for Microbiology Lecturer (1992-94)
National Institutes of Health Wallace Rowe Lecture (1993)
American Cancer Society Faculty Research Grant (1984-1993)
Leukemia Society of America Special Fellow (1981-1983)
Agnes Axtell Moule Faculty Scholar (1983)
Andrew Mellon Fellow (1984)

Professional Affiliations:

American Society for Microbiology
American Society for Virology
American Association of Immunologists

Consultant/Advisory Board Member:

Current Academic Programs:

Louisiana Biomedical Research Network (INBRE), P.I., Klei, Louisiana State University (2004 - present)
Nebraska Center for Virology (COBRE), P.I., Wood, University of Nebraska (2000 - present)

Current Companies:

Scientific Advisory Board, ChemoCentryx (1997-2009)

Past or occasional consulting and scientific advisory board member:

GlobeImmune (2003-2008), Co-crystal Design (2007-2009)Berlex (2005), Genzyme/ILEX (2004-2005), 9th District Court, Judicial Scientific Advisor (2000-2003); ImmunoGen, Inc. (1995-2002); GeneTrol (2001-2002); MedImmune, Inc. (1992-2002) (called Aviron from 1992-2002); Ribozyme Pharmaceuticals, Inc. (1992-2001); Parke-Davis (Warner-Lambert) (1998-1999); Glaxo-Wellcome Herpesvirus Consultancy Group (1996-1998); Searle-Monsanto, Skokie, Illinois (1994-1995); Chiron Corporation, Emeryville, California (1991-92); Schering-Plough, Inc., Madison, New Jersey (1984-1994); Syntro, Inc., San Diego, California (1985-88); SyStemix, Palo Alto, California (1990)

PUBLICATIONS

Journals:

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3. Stinski, M.F., E.S. Mocarski and D.R. Thomsen (1979). Some properties of cytomegalovirus DNA from standard and defective virions. J. Virol. 31:231-239.

4. Post, L.E., A.J. Conley, E.S. Mocarski and B. Roizman (1980). Cloning of reiterated and nonreiterated herpes simplex 1 sequences as BamHI fragments. Proc. Natl. Acad. Sci. USA 77:4201-4205.

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